

# TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
Pu-226 Consent Order.		

## COMMENTS:

EPA Sanitized, Contains No CBI

**SANITIZED**

DOES NOT CONTAIN CBI

EPA SANITIZED

2/29/77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND CONTROL

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

Premanufacture Notice Number:

**CONTAINS NO  
CBI**

P-11-226

2014 FEB 26 PM 2:06

RECEIVED  
OPPT/CBIC

Consent Order, Consent Order for Contract Manufacturer and  
Determinations Supporting Consent Order

**TSCA CONFIDENTIAL  
BUSINESS INFORMATION  
DOES NOT CONTAIN NATIONAL  
SECURITY INFORMATION (E.O. 12067)**

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## PREAMBLE

### I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-11-226 for the chemical substance,

] ("the PMN substance") submitted by [

] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

### II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

- (a) submit to EPA certain tiered toxicity testing before manufacturing the following specified production volume limits of the PMN substance:

Production Volume Limit

Toxicity Testing

Tier I Testing:

90-day oral toxicity in rodents (OPPTS 870.3100) with functional observational battery and neuropathology (OPPTS 870.6200)

Rodent oral dominant lethal assay (OPPTS 870.5450). If positive, an oral rodent heritable translocation test (OPPTS 870.5460) will be required as the follow up test.

Tier II Testing:

2-year oral carcinogenicity test (OPPTS 870.4200) in rats and mice

- (b) provide its workers personal protective equipment to prevent dermal exposure;
- (c) provide respirators to its workers to prevent inhalation exposure;
- (d) as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substance at or below a specified New Chemical Exposure Limit ("NCEL") of  $0.03 \text{ mg/m}^3$ , verified by actual exposure monitoring data (to pursue this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA);
- (e) label containers of the PMN substance and provide Material Safety Data Sheets ("MSDS") and worker training in accordance with the provisions of the Hazard Communication Program section;
- (f) distribute the PMN substance only to a person who agrees to follow the same restrictions (except the testing requirements) and to not further distribute the PMN substance until it has been completely polymerized;
- (g) dispose of the PMN substance only by incineration (destruction and removal efficiency of 99.99%) or underground injection control (class 1 well, deep well injection for hazardous waste);
- (h) comply with the no release to water provisions; and
- (i) maintain certain records.

## THE CONFIDENTIALITY PLEDGE

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order): Submitter identity, chemical identity, production volume, use information, and process information.

### Chemical Identity

Specific: [ ]

Generic: N-(2-hydroxyethyl) alkenamide.

### Use:

Specific: [ ]

)].

Generic: A component of adhesives and cosmetics.

### Maximum 12-Month Production Volume:

### Test Data Submitted with PMN:

- Salmonella assay—negative with and without activation
- E. coli reverse mutation assay—negative with and without activation
- Rat acute oral (gavage) = LD50 > 2.0 g/kg.
- Rat subchronic 28D oral (gavage) = NOEL 50 mg/kg, with neurotoxic and male reproductive system effects.
- Rat acute dermal = LD50 > 2000 mg/kg.
- Minimal eye irritation in male rabbits at 99% ai.
- Not a dermal irritation in male rabbits at 99% ai.

Not a dermal sensitizer (with slight irritation at application site) in female mice at 10% ai.

96 Hour Rainbow trout = LC50 and NOEC is >98 mg/L, the NOEC for mortality is 98 mg/L.

48-hour immobilization test (Daphnia Magna) = LC50 is > 96.4 mg/L, the nominal NOEC for mortality is 96.4 mg/L.

72-Hour Algal study - EC50 is 30.14 mg/L.

#### **IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK**

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

##### **Human Health Effects Summary:**

Absorption: Absorption of the PMN is good all routes based on analog data.

Toxicological Endpoints of Concern: EPA believes that the PMN substance may cause carcinogenicity, heritable mutagenicity, reproductive and developmental toxicity, and neurotoxicity based on data for a number of low molecular weight acrylamides in workers exposed to the PMN substance by the dermal route.

See [www.epa.gov/opptintr/newchems/pubs/chemcat.htm](http://www.epa.gov/opptintr/newchems/pubs/chemcat.htm)

##### **Environmental Effects Summary:**

Based on the submitted aquatic toxicity data on the PMN substance the concentration of concern (COC) was established at 1000 parts per billion.

### Exposure and Environmental Release Summary:

	Process	Use
# Sites		
Workers (total #)		
Exposure (days/year)		
Dermal Exposure (mg/day)	1.8 to 1800	1.8
Inhalation Exposure (mg/day)	Negligible	0.0016 to 0.01
Drinking Water Exposure (mg/day)	0	0
Release to water (kg/day)	0	0

### Risk to General Public:

In 1974, Congress passed the Safe Drinking Water Act. This law requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. Based solely on possible health risk and exposure over a lifetime with an adequate margin of safety, the maximum contaminant level goal (MCLG) for acrylamide is zero. Some people who drink water containing high levels of acrylamide over a long period of time could have nervous system or blood effects and may have an increase risk of cancer.

## V. EPA'S CONCLUSIONS ON LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health effects from exposure to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance.

(b) In light of the potential risk of human health effects posed by the uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

## VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.



## CONSENT ORDER

### I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance [

] (P-11-226) ("the PMN substance") in the United States by [

] ("the Company"), except to the extent that those

activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.2(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely polymerized.

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

## **II. TERMS OF MANUFACTURE, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION**

### **PROHIBITION**

The Company is prohibited from manufacturing, processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

## ENDING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at [www.epa.gov/oppt/tscas8e](http://www.epa.gov/oppt/tscas8e).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

- (1) The date when the study is scheduled to commence;
- (2) The name and address of the laboratory which will conduct the study;
- (3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,
- (4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice

Standards at 40 CFR 161.72 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing the PMN substance beyond the following aggregate volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Volume Limit

Toxicity Testing

Tier I Testing:

90-day oral toxicity in rodents (OPPTS 870.3100) with functional observational battery and neuropathology (OPPTS 870.6200)

Rodent oral dominant lethal assay (OPPTS 870.5450). If positive, an oral rodent heritable translocation test (OPPTS 870.5460) will be required as the follow up test.

Tier II Testing:

2-year oral carcinogenicity test (OPPTS 870.4200) in rats and mice

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable production limit). The testing requirements may be modified, as necessary to permit a reasoned

evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(c) Company Determination of Invalid Data.

(1) Except as described in paragraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture beyond the applicable production limit.

(j) Unreasonable Risk.

EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing

section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant

information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI of this Consent Order.

### PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(2)(i) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Specific Dermal Protective Equipment. The dermal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

(i) Gloves. The following gloves have already been tested resulting in no breakthrough and no permeation by the PMN chemical: North Silver Shield Gloves, Ansell Barrier Gloves, North Butyl Gloves, Ansell Chemi-Pro Gloves, Ansell Neoprene Gloves, Ansell Sol-Vex and Ansell Cannons.

(i) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results shall be reported as the cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this section is provided with and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an Applied Protection Factor ("APF") of 1000, from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.

(5) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

- (i) Particulate (including solids or liquid droplets),
- (ii) Gas/vapor (all substances in the gas form), or
- (iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are both present; a good example is paint spray mist, which contains both liquid droplets and vapor).

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section:

Assigned Protection Factor (APF)	
1,000	<p><u><i>If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:</i></u></p> <p>(I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.</p> <p>(II) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges <i>with evidence demonstrating protection level of 1,000 or greater.</i> ]</p> <p>(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.</p> <p>(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or greater.</i></p> <p>(VI) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.</p> <p><u><i>If No Cartridge Service Life Testing has been Conducted:</i></u></p> <p>(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.</p> <p>(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or greater.</i></p> <p>(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.</p>

- OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

(b) De Minimis Concentrations. The requirements of this section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

### **NEW CHEMICAL EXPOSURE LIMIT**

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substance by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the PMN substance, verified in accordance with subsection (c)(3) of this New Chemical Exposure

Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and,

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substance by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit ("NCEL") for the PMN substance is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substance is as follows:

(i) Time-Weighted Average ("TWA") Limit. The Company shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of  $0.03 \text{ mg/m}^3$  (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(6) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift ( $NCEL_n$ ) shall be determined by the following equation:  $NCEL_n = NCEL \times (8/n) \times [(24-n)/16]$ , where  $n$  = the number of hours in the actual work-shift.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical method for the PMN substance, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(II), (4)(v)(II), (8), and (9). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substance which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN," after which the correct PMN number for this chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company shall have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the PMN substance, in accordance

with the other requirements in this subsection (c)(2). It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substance must comply with TSCA Good Laboratory Practice Standards ("GLP") at 40 CFR Part 792. (Certain provisions of the TSCA GLP applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLP is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company shall collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall

immediately be analyzed by the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company, and the other shall be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v)

or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment C -

Statistical Analysis of NCELS Analytical Method Verification Results.) The average of each set of six samples must be within 10% of the true value. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the true value.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, shall be accurate to within  $\pm 25\%$  at a 95% confidence level for concentrations of the PMN substance ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substance across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(i) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL ( $0.5 \times \text{NCEL}$ ); between one half and one times the NCEL ( $>0.5 \times \text{NCEL}, < 1 \times \text{NCEL}$ ); one times the NCEL ( $1 \times \text{NCEL}$ ); between one and two times the NCEL ( $>1 \times \text{NCEL}, < 2 \times \text{NCEL}$ ), and twice the NCEL ( $2 \times \text{NCEL}$ ).

(ii) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company shall conduct both an initial instrument calibration and a continuing calibration. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall within  $\pm 25\%$  of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(i) Initial Calculation. For method development and validation, the Company must calculate the percent of the PMN substance recovered by the analytical method from a sample containing a known quantity of the PMN substance. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or

equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substance must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substance onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substance is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substance at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is  $30 \text{ mg/m}^3$  and the percent recovery is 75%, use the value  $30 \text{ mg/m}^3 / (0.75) = 40 \text{ mg/m}^3$  when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs (c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive PMN

substance; or introduction of water/increased humidity to the workplace which could react with the PMN substance and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the PMN substance, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company shall take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substance would be if respirators were not worn. The Company shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar

operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substance is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. (Certain provisions of the TSCA GLP applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLP is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA IHLAP; or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for each exposure group.

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substance for each exposure group in which persons are reasonably likely to be exposed to the PMN substance.

(C) Periodic Monitoring

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substance is not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substance is not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 3 month period does not constitute grounds for postponement of the 3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substance is manufactured, processed, or used in

~~separate~~ batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24

hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(1) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substance; and

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the PMN substance.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action.

During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and is able to produce reliable objective data demonstrating that, even under worst-case conditions, employee exposure to

the PMN substance will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Recordkeeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substance and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the PMN substance. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substance, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substance for any person who is reasonably likely to be exposed to the PMN substance by inhalation exceeds the NCEL, the Company shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the PMN substance at a workplace in accordance with this

New Chemical Exposure Limit section, the Company shall comply with the respiratory requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substance by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

#### COMBINATION PARTICULATE AND GAS/VAPOR RESPIRATOR TABLE

Measured  
Concentration  
of PMN Substance

Required Respiratory Protection

= NCEL

No respiratory protection is required.

= 10 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

(I) Any NIOSH-certified **powered air-purifying** respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(II) Any NIOSH-certified continuous flow **supplied-air respirator** equipped with a loose fitting facepiece, hood, or helmet.

If No Cartridge Service Life Testing has been Conducted:

(I) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a loose fitting facepiece, hood, or helmet.

= 25 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

(I) Any NIOSH-certified **powered air-purifying** respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.

(II) Any NIOSH-certified **powered air-purifying** respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(III) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a hood or helmet.

(IV) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a loose fitting facepiece.

*If No Cartridge Service Life Testing has been Conducted:*

(I) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a loose fitting facepiece, hood, or helmet.

(II) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece.

= 50 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

(I) Any NIOSH-certified **air-purifying** full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters.

(II) Any NIOSH-certified **powered air-purifying** respirator with a tight-fitting full facepiece equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(III) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece.

(IV) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a tight-fitting full facepiece.

(V) Any NIOSH-certified pressure-demand or other positive pressure mode **supplied-air** respirator equipped with a tight-fitting full facepiece.

(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

If No Cartridge Service Life Testing has been Conducted:

(I) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting full facepiece.

(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting full facepiece.

(IV) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

= 1000 x NCEL

If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:

(I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.

(II) Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters with evidence demonstrating protection level of 1,000 or greater.

(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater.

(V) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

If No Cartridge Service Life Testing has been Conducted:

(C) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].

(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet *with evidence demonstrating protection level of 1,000 or greater.*

(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].

\* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. **Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.**

> 1000 x NCEL  
(max. 10,000 x  
NCEL)

Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) **self-contained breathing apparatus (SCBA)** equipped with a hood or helmet or a full facepiece.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substance is manufactured,

processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the LQL of the analytical method (as described in paragraph (c)(4)(ii)) is measured, the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (c)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(c) LOEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company shall maintain the following records until 30 years after the date they are created, and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the AIHA or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLP, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results; Any conditions that might

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(vii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substance;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

### **RISK NOTIFICATION**

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to health (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If

the PMN substance is not being manufactured, processed, or used in the Company's workplace,

the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

#### HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to

either a TSCA section 5(c) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at

40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN

substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling.

(1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(1) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheet.

(1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance.

If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

- (i) The requirements of this section.
- (ii) Any operations in the work area where the PMN substance is present.
- (iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

- (i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted

by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health hazards of the PMN substance as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) De Minimis Concentrations. The requirements of this Hazard Communication section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains (1) New Chemical Exposure Limits provisions that specify a NCEL concentration less than the de

minimis concentration specified here, or (2) Release to Water provisions that prohibit release to water or specify in-stream concentration ("TP") less than the de minimis concentration specified here, then this de minimis exemption does not apply to these provisions.

(1) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

- (i) skin irritation.
- (ii) central nervous system effects.
- (iii) internal organ effects.
- (iv) reproductive effects.
- (v) cancer.
- (vi) immune system effects.
- (vii) developmental effects.

(2) Human hazard precautionary statements. When using this substance:

- (i) avoid skin contact.
- (ii) use skin protection.
- (iii) avoid breathing the substance.

(iv) use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of  $0.03 \text{ mg/m}^3$ .

(3) Environmental hazard precautionary statements. Notice to users: can be removed if the substance is not used in a way that could cause environmental harm.

- (i) disposal restrictions apply.

(ii) spill clean-up restrictions apply.

(iii) do not release to water.

(4) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

(g) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

### MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture the PMN substance of the existence of the SNUR.



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(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

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(b) Distribution Requirements. Except after the PMN has been completely polymerized or as provided in paragraph (c), the Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely polymerized.

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace.



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Comply with the laws, regulations and provisions, if any, required of the Company in the Hazard Communication Program section of this Order.

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(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:



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that the Company has, within 15 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

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(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Subparagraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (b)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.



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A promulgates a final SNUR for the PMN substance and subparagraph (b)(2) of this distribution provision expires in accordance with subparagraph (b)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR **OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION** defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (b).

### DISPOSAL

The Company shall dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

(1) The PMN substance must be disposed of only by:

- (i) incineration (destruction and removal efficiency of 99.99%); or
- (ii) underground injection control (class 1 well, deep well injection for hazardous waste);

(2) Waste streams from manufacture must be disposed of only by:

- (i) incineration (destruction and removal efficiency of 99.99%); or



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(1) underground injection control (class 1 well, deep well injection for hazardous waste);

(3) Waste streams from processing must be disposed of only by:

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(i) incineration (destruction and removal efficiency of 99.99%); or

(ii) underground injection control (class 1 well, deep well injection for hazardous waste);

(4) Waste streams from use must be disposed of only by:

(i) incineration (destruction and removal efficiency of 99.99%); or

(ii) underground injection control (class 1 well, deep well injection for hazardous waste);

### RELEASE TO WATER

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. The Company is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing, processing and use containing the PMN substance into the waters of the United States.

### III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:



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Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance

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eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture volume of the PMN substance and the corresponding dates of manufacture;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, processing, and use;



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Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

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(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(7) Records required by paragraph (i). of the New Chemical Exposure Limits section of this Order, if applicable;

(8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(9) Copies of labels required under the Hazard Communication Program section of this Order;

(10) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(11) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(12) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;



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records concerning each chemical and transfer violation procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

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(14) Copies of any Transfer Documents and notices required by the Successor section of this Order, if applicable; and,

(15) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**



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BY EPA ORDER OF THE ADMINISTRATOR

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 120.122, EPA

may occasionally conduct on-site compliance inspections of Company facilities and conveyances

associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the

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Company in advance to request information pertinent to the scheduling and conduct of such

inspections. Such requests may be written or oral. The types of information that EPA may request

include, but are not limited to, the following:

(1) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested

in writing by EPA, the Company's response shall be in writing. To the extent the information is

known to or reasonably ascertainable by the Company at the time of the request, the Company's



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to all of EPA's requests.

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(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

**V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER**

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.



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(c) Definitions. The following definitions apply to the Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to:

U.S. Environmental Protection Agency, New Chemicals Management Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.



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Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must provide provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

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(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor

Successor in Interest



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VI. MODIFICATION, REVOCATION, OR AMENDMENT OF ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of the substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

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EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.



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VII. ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(E), to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

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(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

25 Sept 2013  
Date

Maria J. Doa  
Maria J. Doa, Ph.D., Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

4/14  
Date

Name:

Title:

Company:



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REGULATIONS

*[Note: The attached Order may not contain some of the terms defined below.]*

"Chemical name" means the scientific designation of a chemical substance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation. OFFICE OF CHEMICAL SAFETY  
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"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing salable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.



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"To use." A chemical substance is the "immediate use" of a person, if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, corrosion, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure. OFFICE OF CHEMICAL SAFETY  
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"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency



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...a reasoned evaluation of the potential environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

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"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.



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NOTICE OF TRANSFER

TOXIC SUBSTANCE CONTROL ACT  
SECTION 5(c) CONSENT ORDER

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Company (Transferor)

PMN Number

1. Transfer of Manufacture Rights. Effective on \_\_\_\_\_, the Company did sell or otherwise transfer to \_\_\_\_\_ ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(c) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

- ☐ reasserts,  
☐ relinquishes, or  
☐ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.



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NOTICE OF CHALLENGE TO  
PERMITS SUBSTANCE CONTROL ACT  
SECTION 5(a) (1) (B) (1) (C) (D) (E) (F) (G) (H) (I) (J) (K) (L) (M) (N) (O) (P) (Q) (R) (S) (T) (U) (V) (W) (X) (Y) (Z)

(continued)

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Company (Transferor)

PMN Number

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code



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NOTICE OF TRAILER OF  
TOXIC SUBSTANCES CONTROL ACT  
SECTION 5(c) CONSENT ORDER  
(continued)

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

\_\_\_\_\_  
Successor's Technical Contact

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip Code

\_\_\_\_\_  
Phone



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STATISTICAL ANALYSIS OF ANALYTICAL METHODS  
VERIFICATION RESULTS

This Attachment describes the statistical techniques (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the Chemical Exposure Limit section of this Order. OFFICE OF CHEMICAL SAFETY  
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STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum (\bar{X}_{ij} - \bar{X}_i)^2 / (n_i - 1), i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2) / (W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2 / [W_1^2 / (n_1 - 1) + W_2^2 / (n_2 - 1)]$$

where,

$$W_i = S_i^2 / n_i, i = 1, 2$$

$\bar{X}_1$  = Average of the results from the company laboratory

$\bar{X}_2$  = Average of the results from the independent laboratory

$n_1$  = Number of samples analyzed by the company laboratory

$n_2$  = Number of samples analyzed by the independent laboratory.



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Then compare the absolute value of  $T$  to the 97.5 percentile point of a  $t$  distribution with  $f$  degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general,  $f$  may not be an integer. Use interpolation to obtain the 97.5 percentile point of a  $t$  distribution with  $f$  degrees of freedom.

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**EXAMPLES** --- The following examples (based on simulated data) illustrate the method:

## Example 1

### Data Set 1

80.56  
100.01  
86.04  
52.61  
84.85  
95.75

### Data Set 2

97.11  
102.13  
99.83  
97.83  
105.44  
100.04

$$\bar{X}_1 = 83.30 \quad n_1 = 6$$

$$\bar{X}_2 = 100.40$$

$$n_2 = 6$$

$$S_1^2 = 278.72 \quad W_1 = 46.25$$

$$S_2^2 = 9.26$$

$$W_2 = 1.54$$

$$\text{Absolute value of } T = 2.467$$

$$f = 5.33$$

The  $t$  table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of  $T$ , 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample  $t$  test, the means would be significantly different at the 5% level because the absolute of  $T$  is greater than 2.228, the 97.5 percentile point for the  $t$  distribution with 10 degrees of freedom.

## Example 2

### Data Set 1

82.87  
101.85  
87.44  
99.68  
101.15  
99.21

### Data Set 2

108.05  
96.51  
100.04  
104.33  
110.32  
107.00



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$$\bar{x}_1 = 95.37 \quad n_1 = 6$$

$$\bar{x}_2 = 104.37$$

$$n_2 = 6$$

$$s_1^2 = 65.59 \quad W_1 = 10.93$$

$$s_2^2 = 27.25$$

$$W_2 = 4.54$$

$$\text{Absolute value of } T = 2.290$$

$$f = 8.54$$

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The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.